No. 01-188

IN THE

Supreme Court of the United States

PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA,

Petitioner,

v.

KEVIN CONCANNON, COMMISSIONER, MAINE DEPARTMENT OF HUMAN SERVICES, AND G. STEVEN ROWE, ATTORNEY GENERAL OF MAINE,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the First Circuit

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QUESTIONS PRESENTED

1. Whether the federal Medicaid statute, 42 U.S.C. § 1396 *et seq.*, precludes Maine from limiting Medicaid patients' access to prescription drugs as a means of compelling drug manufacturers to subsidize price discounts for non-Medicaid populations?
2. Whether Maine violates the Commerce Clause by requiring an out-of-state manufacturer that sells its products to wholesalers outside the state to remit a payment to the state each time one of the manufacturer's products is subsequently sold by a retailer within the state?

PARTIES TO THE PROCEEDING

Petitioner is the Pharmaceutical Research and Manufacturers of America ("PhRMA"). Respondents are Kevin Concannon, the Commissioner of the Department of Human Services of the State of Maine, and G. Steven Rowe, the Attorney General of the State of Maine.

Petitioner PhRMA is a not-for-profit incorporated membership organization. There are no parent corporations or publicly held companies that own 10% or more of PhRMA's stock. A list of PhRMA's members is found at http://www.phrma.org/whoweare/members/memlist.phtml?mbrType=members#membersListStart.

TABLE OF CONTENTS

TABLE OF CONTENTS—continued

TABLE OF AUTHORITIES

CASES Page

TABLE OF AUTHORITIES—continued

CONSTITUTION, STATUTES AND REGULATIONS

LEGISLATIVE HISTORY

TABLE OF AUTHORITIES—continued

SCHOLARLY AUTHORITY

OTHER AUTHORITIES

TABLE OF AUTHORITIES—continued

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1-53) is reported at 249 F.3d 66 (1st Cir. 2001). The opinion of the district court (Pet. App. 57-72) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on May 16, 2001. On June 13, 2001 the court of appeals entered an order denying rehearing and declining action on PhRMA's timely petition for rehearing *en banc* for lack of a quorum of judges able to act on the petition. PhRMA filed its petition for a writ of certiorari in this Court on July 31, 2001. The Court issued an order granting the petition on June 28, 2002.

The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

1. Article I, Section 8, Clause 3 of the Constitution provides, in pertinent part, that "The Congress shall have Power … To regulate Commerce … among the several States."
2. Article VI, Section 2 of the Constitution provides, in pertinent part, that "This Constitution, and the Laws of the United States which shall be made in Pursuance thereof … shall be the supreme Law of the Land."
3. Title XIX of the Social Security Act governing the Medicaid Program, with particular reference to Section 1927 of the Act, 42 U.S.C. § 1396r-8, is reproduced in pertinent part at Pet. App. 73-84 and JA 253-60.
4. The Act to Establish Fairer Pricing for Prescription Drugs, 2000 Me. Legis. Ch. 786 (S.P. 1026) (L.D. 2599) ("Maine Rx") is reproduced at Pet. App. 85-108.

STATEMENT OF THE CASE

This lawsuit challenges a Maine statute that restricts Medicaid patients' access to a manufacturer's drugs within the Medicaid program unless the manufacturer pays for price subsidies for non-Medicaid Maine consumers. If such payments are not made, Maine will subject the manufacturer's drugs to a "prior authorization" requirement, resulting in reduced access to those drugs for Medicaid beneficiaries and sharp reductions in the manufacturer's sales. The "Maine Rx" program thus leverages regulatory powers that Congress gave Maine to operate the Medicaid program to obtain funds from manufacturers to pay for a non-Medicaid program. This is flatly inconsistent with the Medicaid statute's mandate that Medicaid state plans be operated "consistent with ... the best interests of recipients." 42 U.S.C. § 1396a(a)(19). Holding Medicaid patients hostage to Maine's effort to reduce the costs of prescription drugs paid by other Maine residents interferes with the achievement of Congress's objectives in Medicaid and does so without any corresponding benefit to that federal program. It is therefore preempted under the Supremacy Clause.

This lawsuit also challenges Maine's demand for payments from manufacturers under the Commerce Clause. Out-of-state manufacturers whose only sales leading to the pharmacy counter take place outside Maine cannot be required to pay "rebates" to the state. Maine's demand regulates transactions occurring wholly outside Maine's borders, and confers a discriminatory subsidy on Maine consumers. Maine Rx thus violates the fundamental principle that a state may not achieve its social goals by regulating commerce in other states or shifting the costs of in-state benefits onto out-of-state interests.

I. THE MEDICAID PROGRAM

A. Congress created the Medicaid program in 1965 to provide medical care to eligible low-income individuals. The primary objective of the Medicaid program is:

> to furnish (1) medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services, and (2) rehabilitation and other services to help such families and individuals attain or retain capability for independence or self-care.

Id. § 1396.

States that elect to participate in the Medicaid program receive federal funds to reimburse specified percentages of the states' expenditures on medical assistance. Each state must submit to the federal government for approval a plan setting out the medical assistance that it will provide. *Id.* § 1396a(a). Congress has specified certain categories of needy individuals who must be eligible for Medicaid benefits provided by a state; states have discretion to extend benefits to additional "medically needy" populations. *Id.* § 1396a(a)(10)(A), (C). The statute sets forth a number of requirements for state plans, including the requirement that they "provide such safeguards as may be necessary to assure that ... care and services will be provided, in a manner consistent with simplicity of administration and the best interests of recipients." *Id.* § 1396a(a)(19).

Under section 1927 of the Social Security Act ("SSA"), *id.* § 1396r-8, states may choose to provide a Medicaid prescription drug benefit and pay for drugs prescribed to Medicaid beneficiaries. As a condition of coverage of their drugs nationwide in the Medicaid program, drug manufacturers must agree to pay a "rebate" to each state on drugs used in treating Medicaid beneficiaries and paid for by the state. *Id.* § 1396r-8(a), (b)(1)(A). Manufacturers enter

into a national agreement with the Secretary of the Department of Health and Human Services ("HHS") to provide those rebates. Notice, 56 Fed. Reg. 7049 (Feb. 21, 1991).[1]

The Medicaid statute permits the states to impose certain access limitations on prescription drugs covered under their state plans. For example, states may maintain formularies, or lists of drugs that are preferred and covered by Medicaid without further restrictions, as long as, *inter alia*, any exclusions from those lists are based on written clinical assessments of the drugs. 42 U.S.C. § 1396r-8(d)(4). States may also subject covered drugs to "prior authorization," *id.* § 1396r-8(d)(1)(A). If a drug is subject to a prior authorization requirement, it will be paid for by Medicaid only if the prescribing physician first obtains patient-specific approval from state Medicaid authorities or their designated agents. The prior authorization system must at a minimum include specified procedural safeguards—namely, that prior authorization requests will receive a response within 24 hours, and that in emergency situations 72-hour supplies of drugs will be provided while requests are pending. *Id.* § 1396r-8(d)(5).

B. Prior authorization is used in the Medicaid program in conjunction with other limitations on prescription drug access spelled out in the statute. Such uses for prior authorization include policing quantity and refill limits for waste, fraud and abuse purposes, *id.* § 1396r-8(d)(6), and monitoring for

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[1] The nationwide Medicaid rebate for a given drug is calculated based on data about the manufacturer's pricing around the country, using a formula set forth in the Medicaid statute. 42 U.S.C. § 1396r-8(c)(1). For brand-name (single source or innovator multiple source) drugs, the rebate is the greater of either (i) 15.1% of the average manufacturer price, or (ii) the difference between the average manufacturer price and the manufacturer's "best price," defined as its lowest price to any private or public purchaser (with limited exceptions) anywhere in the United States. *Id.* § 1396r-8(c)(1)(A)-(C).

inappropriate or contraindicated uses identified by Medicaid Drug Use Review committees, *id.* § 1396r-8(g). If a state creates a drug formulary, it must also employ a prior authorization program to allow beneficiary access to drugs not on the formulary. *Id.* § 1396r-8(d)(4)(D).

A state may impose Medicaid prior authorization requirements only pursuant to a state plan approved by HHS. *Id.* § 1396r-8(d)(1), (5). A state must amend its state plan, and submit the amendment to HHS for approval, "whenever necessary to reflect…[m]aterial changes in State law, organization, or policy, or in the State's operation of the Medicaid program." 42 C.F.R. § 430.12(c)(ii).

C. Although Congress allowed it for these Medicaid uses, prior authorization indisputably burdens Medicaid patients and physicians, as the district court found (Pet. App. 68). It limits—indeed is meant to limit—Medicaid patients' access to drug therapies that otherwise would be readily available, and deters physicians from prescribing their first-choice drugs when those drugs are subject to prior authorization (JA 102-05, 111-12). This is so because the pressures of modern medical care mean that physicians have incentives to avoid cumbersome and time-consuming prior authorization requests by forgoing prescribing first-choice drugs in favor of different drugs for which prior authorization is not required (JA 104-05).[2] The deterrent effect is magnified when the state requires the physician to make a substantial showing to obtain prior authorization, or indicates that drugs will not be authorized unless other drugs have already been tried and failed. See, *e.g.*, *Maine Medical Assistance Manual* ch. II

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[2] According to a recent study, the mean duration of an office visit in 1998 was 18.3 minutes per patient. *See* David Mechanic et al., *Are Patients' Office Visits with Physicians Getting Shorter?*, 334 New Eng. J. Med. 198, 200 fig.1 (2001). If the physician must dedicate an additional 15 or 20 minutes to preparing a written request for prior authorization to be submitted to the state Medicaid authorities, he or she will be able to see one fewer Medicaid patient.

§ 80.07-3 (2002) (requiring written prior authorization request), *available at* ftp://ftp.state.me.us/pub/sos/cec/rcn/apa/10/144/ch101/c2s080.doc; State of Me. Dep't of Human Servs., Prior Authorization Form, Miscellaneous Drugs Subject to PA (requiring explanation of "why … this medication [is] medically necessary" and "what other alternatives were tried first"), *available at* http://www.ghsinc.com/Japps/upload/Miscellaneous.doc (last visited Sept. 19, 2002).[3]

Prior authorization requirements also subject patients to delay, anxiety, and even adverse health outcomes (JA 105). Medicaid patients may well learn about prior authorization for the first time at the pharmacy counter, when they are told that Medicaid will not cover their drug without it. There is a serious risk that patients will not follow up and ask their physicians to seek prior authorization, and will instead go without the prescribed drug therapy. See Owens et al., Florida Ctr. for Medicaid Issues, *Florida Medicaid Prescribed Drug Program, Four Brand Prescription Limit Policy: Final Report – Phase I*, at L04-L05 (June 2001) (see Petitioner's Lodging filed Sept. 20, 2002).[4] This may cause delay and even a second trip to the pharmacy, even if the physician proves willing to run the prior authorization

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[3] *Cf. Maine Medical Assistance Manual Proposed Rules* ch. II § 80.07-3 (2001) (JA 288) (listing required information, subsequently revised to require submission of form request).

[4] This recent study of Florida's Medicaid program, which required prior authorization for any prescription over a four-drug-per-patient limit, illustrates the likely outcomes. Out of some 155,000 instances in which pharmacies rejected prescriptions lacking prior authorization, in about 60% of the cases the prescribing physician then declined to pursue prior authorization. Some portion of that figure may represent cases in which the physician switched the patient to second-choice drugs rather than attempt to navigate through the prior authorization process. But the study reports that in over 25% of those cases, *no drug was dispensed* to the patient at all. Owens et al., *supra*, at L04-L05.

gauntlet (JA 105). The confusion and possible medical consequences are serious. See, *e.g.*, Roberta Scruggs, *Medicaid Patients Feel Sting of New Drug Rules*, Portland Press Herald, Feb. 4, 2001 (reporting patient harm, including hospitalization, in wake of expanded prior authorization requirements in Maine) (see Petitioner's Lodging filed Sept. 20, 2002).

These effects on patients and physicians are mirrored by the consequences for the companies supplying drugs that are subject to prior authorization. Drug manufacturers' experience indicates that subjecting a drug to prior authorization results in drastic losses of market share and severely reduced sales (JA 57-58, 102-06, 111-14).

II. THE MAINE RX PROGRAM

A. Maine's Act to Establish Fairer Pricing for Prescription Drugs , 22 Me. Rev. Stat. Ann. § 2681 *et seq*. (the "Act") (Pet. App. 85-108), requires drug manufacturers who participate in the national Medicaid program to subsidize retail price discounts to Maine residents under a new state program called "Maine Rx." Unlike Medicaid, the Maine Rx program is open to all residents of the state without regard to income or medical need.[5]

The Act requires all drug manufacturers whose products are ultimately sold in Maine to beneficiaries of public pharmaceutical assistance programs to enter into "rebate agreement[s]" with the state, separate and apart from their national Medicaid rebate agreements, that obligate them to

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[5] The Maine Rx program is open to any "qualified resident," defined as "a resident of the State who has obtained from the department [of Human Services] a Maine Rx enrollment card." 22 Me. Rev. Stat. Ann. § 2681(2)(F), (5) (Pet. App. 87, 88). The Commissioner's proposed implementing regulations specify Maine residency as the sole criterion for eligibility for the program. *See Proposed Rules of the Department of Human Services* ch. 130 §§ 1.3-.5 (proposed Oct. 5, 2000) (not finalized) (JA 311-12) .

make payments to a segregated fund used to subsidize retail price discounts for Maine Rx participants. *Id.* § 2681(3) (Pet. App. 87). Because manufacturers' drugs are sold nationwide (including in Maine) under Medicaid, manufacturers' participation in that federal program automatically subjects them to Maine's new rebate requirements.

Signing the Maine Rx rebate "agreement" is mandatory. The Act states that a manufacturer "shall enter into" the required agreement, *id.*, and, as discussed below, penalizes manufacturers that do not enter into such agreements by subjecting their drugs to prior authorization in the Medicaid program, *id.* § 2681(7) (Pet. App. 89-90).

Under the agreement, a manufacturer must make a "rebate" payment to the state for each unit of a drug that is sold by a Maine pharmacy to a participating Maine resident. *Id.* § 2681(3) (Pet. App. 87); Maine Rx Program Rebate Agreement (JA 169-79). Manufacturer payments are to be paid into a dedicated state fund, which Maine will use to reimburse local retail pharmacies for prescription drug discounts for participating Maine residents.

Maine residents will tender a "Maine Rx" card at the pharmacy, and will be charged a discounted price set by the state. The state will then use the funds obtained from manufacturers to reimburse pharmacies for those discounts, plus "professional fees" of at least $3 per prescription. 22 Me. Rev. Stat. Ann. § 2681(5), (6) (Pet. App. 88-89). Maine makes no net contribution to these subsidies; they are to be funded entirely by the payments extracted from manufacturers.

B. The Act enforces its requirement that manufacturers pay for these non-Medicaid Maine Rx subsidies by threatening them with, *inter alia*, sanctions under the federal Medicaid program if they do not. If a manufacturer refuses to pay Maine Rx rebates, its drugs will be subject to a prior authorization requirement in the Medicaid program in Maine.

Id. § 2681(7) (Pet. App. 89-90).[6] A drug subject to prior authorization will not be available to Medicaid beneficiaries unless a physician first obtains special permission from state Medicaid officials or their agents to prescribe it to a Medicaid patient. Thus, the Act uses a Medicaid process, affecting Medicaid patients, to extract payments to subsidize non-Medicaid drug purchases.

To obtain prior authorization in Maine's Medicaid program, a physician must contact the Medicaid Pharmacy Program Coordinator and make a request in writing for permission to prescribe a listed drug to her Medicaid patient. *Maine Medical Assistance Manual* ch. II, § 80.07-3. At a minimum, the request must include the physician's explanation of why the medication is necessary, and what other alternatives (if any) were tried first. State of Me. Dep't of Human Servs., Prior Authorization Form, Miscellaneous Drugs Subject to PA.[7] For Maine Rx purposes, Maine has been clear that "it

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[6] The Act also penalizes such manufacturers by publicizing their noncompliance with the Act, 22 Me. Rev. Stat. Ann. § 2681(7) (Pet. App. 89-90), and threatens them with prosecution under so-called "anti-profiteering" provisions that create private and public causes of action for civil penalties and treble damages against anyone who "[e]xtracts or demands an unconscionable price," or obtains an "unjust or unreasonable profit" in sales of prescription drugs, *id.* § 2697(2) (Pet. App. 98-99). PhRMA obtained (and Maine has not appealed from) preliminary injunctive relief against the latter with respect to sales made outside Maine.

[7] Maine's process requires additional documentation for prior authorization of specific categories of drugs, such as NSAIDs and Cox-2 inhibitors for arthritis treatment, weight loss drugs, and growth hormones. The 20 different forms are available online at http://www.ghsinc.com/Japps/servlet/NewPAPage (last visited Sept. 19, 2002). To obtain certain non-sedating allergy drugs, for example, the physician must either certify that the patient "[f]ailed on at least 2 less costly antihistamines" or attach documentation of actual adverse effects of other, sedating allergy drugs on the patient's school or work performance. State of Me. Dep't of Human Servs., Prior Authorization Form, Non Sedating Antihistamines, *available*

will not authorize payment for the first choice drug manufactured by a [Maine Rx] non-participant where there is another drug for the ailment manufactured by a participant" (Pet. App. 15).

Maine has neither sought nor received HHS approval to amend its state Medicaid plan to incorporate the Maine Rx prior authorization sanctions. *Cf.* 42 U.S.C. § 1396r-8(d)(1), (5); 42 C.F.R. § 430.12(c)(ii). Nor has Maine limited the prior authorization requirements to those that serve Medicaid or even medical purposes, such as controlling over-prescription or guarding against drug interactions. Rather, Maine Rx will subject drugs (and Medicaid patients and physicians) to prior authorization solely because doing so will have the effect of punishing non-complying manufacturers by reducing their sales. Manufacturers know and expect that physicians will avoid the prior authorization process, and that physicians may not succeed in obtaining prior authorization even if they seek it. Accordingly, manufacturers understand that a refusal to pay the non-Medicaid rebates that Maine demands will mean that their drugs will not be prescribed to Medicaid beneficiaries in many cases where they otherwise would be prescribed (JA 57-58, 102-06, 111-14).

C. The Act requires pharmaceutical manufacturers to make rebate payments even if they are complete strangers to the in-state pharmacy sales transaction, and even if the manufacturer never engaged in *any* sales transaction in Maine leading up to that retail purchase. It is undisputed that there are currently no drug manufacturers located in Maine, and that manufacturers make few (if any) sales directly to anyone in Maine, much less retail sales to consumers (JA 50-51, 56-57, 76-77, 87-88, 110-11). Typically, pharmaceutical manufacturers sell drugs to national and regional wholesalers (all but one of which are also outside Maine) in transactions that

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at http://www.ghsinc.com/Japps/upload/Non_Sedating_Antihistamines.doc (last visited Sept. 19, 2002).

take place in other states (*id.*). Thus, the Maine Rx "rebate" is extracted by the state not from the actual in-state seller, or from any party to an in-state transaction; it is obtained from the out-of-state manufacturer, who makes only the first sale—to an out-of-state wholesaler—of a drug that ultimately is dispensed in Maine.

The "rebate" required from a manufacturer is set by reference to a national price benchmark: the rebate paid by manufacturers nationwide in the Medicaid program. The Maine Commissioner of Human Services is instructed to use his "best efforts"—backed by the sanctions of the Act—to secure a rebate for each drug that is at least as large as the federal Medicaid rebate amount. 22 Me. Rev. Stat. Ann. § 2681(4)(B) (Pet. App. 88). Implementing the Act's mandate, Respondent Concannon presented manufacturers with a form Maine Rx Program Rebate Agreement that dictated payment of "the Medicaid Rebate amount" (JA 62, 65, 89, 92). In later stages, the Act directs that the Maine Rx rebate shall match or exceed the rebates or price discounts in an additional category of out-of-state sales—namely, manufacturers' sales to any part of the federal government. 22 Me. Rev. Stat. Ann. § 2681(4)(C) (Pet. App. 88).

III. PROCEEDINGS BELOW

A. On August 10, 2000, PhRMA filed its complaint for declaratory and injunctive relief in the United States District Court for the District of Maine, claiming that the rebate provisions of the Act violate the Supremacy and Commerce Clauses of the U.S. Constitution. On October 26, 2000, finding PhRMA's likelihood of success on the merits of these claims to be "overwhelming," the district court issued a preliminary injunction against the implementation of the Maine Rx rebate program (Pet. App. 72).

The district court held that Maine had exceeded the territorial limits of its regulatory authority under the Commerce Clause. The district court found that, by exacting

rebates from drug manufacturers who sell their drugs outside the state, the Maine Rx Program unavoidably—and unconstitutionally—regulates those out-of-state sales (Pet. App. 64-66).

The district court also ruled that Maine's use of its Medicaid prior authorization power to penalize manufacturers who do not subsidize discounts under the non-Medicaid Maine Rx program necessarily burdened Medicaid recipients and posed an obstacle to Congress's express purpose of delivering Medicaid benefits to participants in that program. Because of that conflict between Maine and federal law, the district court found that the use of prior authorization to enforce Maine Rx rebate collections is preempted (Pet. App. 67-70).

B. On May 16, 2001, a panel of the court of appeals for the First Circuit reversed and vacated portions of the preliminary injunction (Pet. App. 28). The court of appeals held that, because the triggering pharmacy sales of the drugs take place in Maine, the effects of Maine's rebate demands do not constitute "extraterritorial" or discriminatory regulation in violation of the Commerce Clause.

The court of appeals also held that Maine's use of the Medicaid "prior authorization" sanction to compel payment of subsidies for *non*-Medicaid patients under Maine Rx does not inexorably conflict with the Medicaid program. The court declined to find a conflict absent evidence that prior authorization absolutely denies medically necessary drugs to Medicaid patients (Pet. App. 16). The court also expressed the view that Maine Rx subsidies might benefit the Medicaid program indirectly by potentially keeping some Maine residents from needing Medicaid assistance at some future date (*id*. at 13).

PhRMA timely sought rehearing. The court of appeals determined that the court could not act on the petition for rehearing *en banc* because all but one of the active judges of

the court were recused. The one active judge of the First Circuit who was not recused—Chief Judge Toruella—voted to rehear the case *en banc* "based on the opinion of the District Court" (Pet. App. 55). The court subsequently entered a stay of its mandate pending certiorari, which PhRMA timely sought on July 31, 2001 (JA 31-32). As a result, the Maine Rx program remains subject to the preliminary injunction against its implementation.

This Court granted review on June 28, 2002.

SUMMARY OF THE ARGUMENT

The Maine Rx program violates both the Supremacy and Commerce Clauses of the Constitution. Accordingly, the judgment below should be reversed.

By definition and by design, the Maine Rx program restricts Medicaid patient access to prescription drugs. Requiring prior authorization makes it more difficult for Medicaid patients to obtain the restricted drugs and drastically reduces sales of those drugs. Medicaid patients (and the drug manufacturers who would supply them) can be ransomed from this restriction only if the manufacturers make payments to the state. Those payments do not benefit the Medicaid patients whose ready access to prescription drugs is put at risk. Instead, they benefit other residents of the state. But federal law does not permit Maine to threaten Congress's intended beneficiaries in order to benefit other Maine residents. The use of regulatory powers granted by Congress for use in Medicaid, to ends that do not serve and and even burden Medicaid patients and the Medicaid program, is preempted as an obstacle to the achievement of Congress's purposes in the federal Medicaid statute.

Not only does the Maine Rx statute use Medicaid powers for non-Medicaid purposes, it also regulates conduct occurring wholly outside the state. Maine Rx requires every drug manufacturer in the nationwide Medicaid program to

pay the state each time *someone else* sells its drug to a Maine resident. But drug manufacturers are located outside Maine, sell almost exclusively to wholesalers outside Maine, and do not participate in the retail Maine Rx sales that take place in Maine. By sending a bill to a manufacturer, Maine is necessarily regulating the only sale the manufacturer does make in the chain of transactions leading to Maine—the wholesale sale outside Maine. Moreover, Maine ties the payments it demands to the prices charged by manufacturers outside Maine, throughout the country, in the Medicaid program and in sales to the federal government. This has the effect of regulating the prices manufacturers charge outside Maine. The Commerce Clause, however, forbids states from regulating prices and transactions in other states, and from exporting the costs of in-state subsidies to out-of-state entities. The Maine Rx rebate is therefore unconstitutional under the Commerce Clause.

ARGUMENT

I. MAINE'S USE OF MEDICAID PRIOR AUTHORIZATION POWERS FOR NON-MEDICAID PURPOSES CONFLICTS WITH THE FEDERAL MEDICAID STATUTE.

The Maine Rx program constricts the flow of prescription drug benefits to Congress's intended beneficiaries of Medicaid. This restraint does not advance clinical interests, or promote the interests of Medicaid patients or the Medicaid program. The sole purpose and effect of Maine's program is to coerce manufacturers to provide the state with funds to subsidize the drug purchases of a non-Medicaid population—namely, all other residents of Maine.

In effect, Maine is holding Medicaid patients' prescription drug benefits hostage to the state's fundraising efforts on behalf of others outside the Medicaid program. Such leveraging necessarily conflicts with the Medicaid statute.

Maine may not use a regulatory power conferred by Congress for use in Medicaid to the disadvantage of the very patients Congress intended to assist, or to undermine a careful bargain struck by Congress in the Medicaid statute.

State laws that impose obstacles to the accomplishment and execution of the Congressional objectives of a federal statute—here, Medicaid—cannot stand. *Pacific Gas & Elec. Co.* v. *State Energy Res. Conservation & Dev. Comm'n*, 461 U.S. 190, 204 (1983); see also *Gade* v. *National Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98 (1992); *Felder* v. *Casey*, 487 U.S. 131, 138 (1988); *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941). Maine Rx is just such a law. It is in actual conflict with the "structure and purpose of the statute as a whole," *Gade*, 505 U.S. at 98 (citing *Pilot Life Ins. Co.* v. *Dedeaux*, 481 U.S. 41, 51 (1987)) because it burdens Medicaid beneficiaries without serving any Medicaid purpose.

A. Prior Authorization Burdens Medicaid Prescription Drug Benefits.

It should be beyond dispute that, as the district court found (Pet. App. 68) and as the Solicitor General observed in his *amicus curiae* brief at the certiorari stage, Maine Rx's prior authorization requirement "burden[s] the ability of Medicaid recipients to receive covered drugs." U.S. Br. at 11.

Prior authorization is by definition a procedural obstacle to providing physicians' first-choice drugs to Medicaid beneficiaries. The prior authorization process interferes with the physician's free selection of medications to treat his or her Medicaid patient, forcing the physician to choose between a first-choice drug that requires prior authorization and a second-choice, possibly less effective, drug that does not. Prior authorization requirements either deter physicians from prescribing drugs that would otherwise be their first choice, or consume the physicians' precious time and resources if they do prescribe those drugs.

In other words, but for a prior authorization requirement, any drug of a manufacturer participating in the national Medicaid program would be readily accessible to Medicaid patients and physicians without delay, and paid for by Medicaid without reservation. Once a prior authorization requirement is in place, however, a listed drug is no longer routinely available—it is available to the Medicaid beneficiary only if the patient's physician undertakes the cumbersome process of seeking authorization from state Medicaid officials, and ultimately succeeds in that effort.

In addition, Maine Rx-triggered prior authorization burdens the Medicaid program. It consumes federally-funded Medicaid resources, including the time and resources of the Medicaid Drug Utilization Review Committee that lists drugs for prior authorization, see 42 U.S.C. § 1396r-8(g); *Maine Medical Assistance Manual Proposed Rules* ch. II § 80.05-3 (proposed Oct. 5, 2000) (not finalized) (JA 278); *Proposed Rules of the Department of Human Services* ch. 130 § 1.15 (proposed Oct. 5, 2000) (not finalized) (JA 320), and of the Medicaid officials who must review physicians' prior authorization requests, *Maine Medical Assistance Manual Proposed Rules* ch. II § 80.07-3.

Maine has suggested that some drugs from nonparticipating manufacturers might not be prior authorized if they have unique therapeutic properties, and that some prior authorization requests will be granted if the physician can make the case that the chosen drug is "medically necessary."[8] But these assertions are beside the point. It is indisputable that prior authorization under Maine Rx will restrict Medicaid

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[8] Maine cited changes to the Maine Medicaid regulations that the Commissioner proposed (but did not finalize) for purposes of implementing the Maine Rx program's prior authorization sanction. *See Maine Medical Assistance Manual Proposed Rules* ch. II § 80.05-3 (JA 278); *Proposed Rules of the Department of Human Services* ch. 130 § 1.15 (JA 320).

beneficiaries' access to prescription drugs; it cannot otherwise achieve its coercive effect. If the failure to pay Maine Rx rebates will not trigger prior authorization of at least *some* drugs—indeed, a substantial number of drugs—that would otherwise be readily available in Medicaid, the threat of prior authorization would be useless to Maine as a tool to coerce rebate payments from manufacturers. Likewise, no matter how the program is implemented, and regardless of whether a given physician can ultimately establish to Maine's satisfaction that a particular prescription drug is medically necessary, the prior authorization process interferes with the physician's free selection of medications to treat his or her Medicaid patient. As the district court found, while "the parties disagree on the severity of the obstacle," prior authorization "*is* an obstacle" (Pet. App. 68 (emphasis added)). This interference with the physician's choice of treatments for Medicaid patients is inherent and inescapable in the structure of the program.

The burden that prior authorization necessarily inflicts on Medicaid patients, doctors, and drug company sales is sufficient on its face to make out PhRMA's preemption case. PhRMA need not prove that prior authorization ultimately results in actual harm to the health of Medicaid beneficiaries.

Nevertheless, prior authorization does have significant, real-life consequences for Medicaid patients, physicians, and pharmaceutical companies. Prior authorization consumes precious time and resources, and artificially deters physicians from prescribing drugs that would otherwise be their first choice. It also burdens Medicaid patients, who may be put through trial-and-error routines on second-choice drugs in order to prove that they need a drug subject to prior authorization. Those same Medicaid patients, who by definition lack the financial resources to opt out, can also find themselves at pharmacy counters without the drugs their doctors have told them they need, and without the means to navigate the prior authorization bureaucracy. Though the

prior authorization obstacle may be procedural, the health consequences if patients are denied, or abandon the quest for, therapeutic prescription drugs are very real. Were there clinical or otherwise federally sanctioned reasons to take such risks with Medicaid patients' health, these consequences could be tolerable. But Maine Rx prior authorization will inflict such risks arbitrarily, based solely on whether a drug manufacturer has submitted to subsidizing a non-Medicaid program.

B. Prior Authorization For Non-Medicaid, Maine Rx Reasons Conflicts With The Object And Purpose Of Medicaid.

Although prior authorization by definition restricts the provision of physicians' first-choice drugs to Medicaid patients, Congress nevertheless decided that for certain uses the burden was outweighed by the benefits to the Medicaid program. See H.R. Rep. No. 101-881, at 98 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2110. The federal Medicaid statute thus permits states to impose prior authorization requirements for prescription drugs paid for by Medicaid consistent with the statute, and subject to certain procedural safeguards. 42 U.S.C. § 1396r-8(d)(1), (5). It is used, for example, to prevent abuse or over-prescription of popular but expensive medications. See *id.* § 1396r-8(g). It is also used to ensure that Medicaid beneficiaries have access to prescription drugs that have been excluded from states' clinically-based formularies when the drug is medically necessary for the patient. *Id.* § 1396r-8(d)(4). Both uses benefit Medicaid patients and promote Medicaid's efficient operation, as required by the statute. *Id.* § 1396a(a)(19), (30).

Here, however, the purpose of burdening Medicaid patients' access to drugs is not to benefit the Medicaid program or Medicaid beneficiaries, but to coerce funding by drug manufacturers of an unrelated state program from which Medicaid patients derive no benefit. "[T]he question whether

a certain state action is pre-empted by federal law is one of congressional intent. The purpose of Congress is the ultimate touchstone." *Gade*, 505 U.S. at 96 (alteration in original) (internal quotation marks omitted). Congress did not intend to allow Medicaid to be impaired solely to promote a state's non-Medicaid objectives.

1. Maine Rx Conflicts With Congress's Purpose Of Assisting Medicaid Beneficiaries.

The federal statute states that the Medicaid program's object and purpose is "to furnish … medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services." 42 U.S.C. § 1396. Its actual scope, however, is considerably more specific. Congress intended to provide medical assistance such as prescription drugs specifically to Medicaid beneficiaries—a class identified by federal law that does not extend to the entire citizenry of Maine. See *id.* §§ 1396, 1396a(a)(10)(A), (C), 1396d(a); cf. *Schweiker* v. *Hogan*, 457 U.S. 569, 590 (1982) (citing legislative history that Medicaid beneficiaries are "'the most needy in the country and it is appropriate for medical care costs to be met, first, for these people'").

It is not enough that Maine Rx and Medicaid both seek to facilitate access to medical assistance (here, prescription drugs). State legislation that serves the same general ends as a federal statute can nonetheless run afoul of it on preemption grounds, by interfering impermissibly with Congress's objectives and the means chosen to implement them. See, *e.g.*, *Crosby* v. *National Foreign Trade Council*, 530 U.S. 363, 379-80 (2000). More important, Maine Rx and Medicaid do *not* serve the same objectives. Medicaid offers medical assistance to specified classes of needy beneficiaries, while Maine Rx offers retail discounts to all Maine residents (no matter how capable they are of paying non-rebated

prices), and does so by burdening Medicaid beneficiaries and the Medicaid program.

The Medicaid statute specifies that the goal of providing medical assistance must be implemented by the states in certain ways. See generally 42 U.S.C. § 1396a (listing requirements for state Medicaid plans). Of particular importance, § 1396a(a)(19) directs that state plans must "assure that … care and services will be provided[] in a manner consistent with simplicity of administration and the best interests of recipients." Using Medicaid prior authorization for the benefit of non-Medicaid populations clearly violates this requirement. Congress's overarching objective is to provide medical assistance to specified beneficiaries. But the burden of Maine Rx prior authorization will be imposed on those very Medicaid beneficiaries solely in order to further Maine's interest in raising funds for non-Medicaid state residents. That burden in no way furthers, or pays any heed whatsoever to, the "best interests" of Medicaid recipients.

And far from simplifying Medicaid administration, Maine Rx adds to the program's administrative burden. Drugs never before involved in the Medicaid program's prior authorization system (namely, the drugs of nonparticipating manufacturers) will have to be reviewed by the Medicaid Drug Utilization Review Committee. Medicaid officials and contractors will have to review and respond to more prior authorization requests, and they will be evaluating physicians' "medical necessity" arguments for unfamiliar drugs that are new to the prior authorization system.

2. Maine Rx Conflicts With The Balance Struck By Congress In The Medicaid Drug Rebate Program.

The Maine Rx program also conflicts with Congress's specific objectives and purposes in creating the Medicaid prescription drug rebate program.

Prior to 1990, many states that provided a prescription drug benefit to Medicaid patients did so only on a limited basis. Congress grew concerned that states were cutting costs by restricting the range of drugs for which Medicaid would make payment, thereby depriving Medicaid beneficiaries of the full range of up-to-date FDA-approved drug therapies.[9] At the same time, there was concern that Medicaid prescription drug expenditures were growing and that state Medicaid programs might be paying too much for covered drugs. As a result, in section 4401 of the Omnibus Budget Reconciliation Act of 1990 ("OBRA 90"), Pub. L. No. 101-508, 104 Stat. 1388, 1388-143 to 1388-159, Congress enacted SSA section 1927 (codified at 42 U.S.C. § 1396r-8). This legislation struck a deliberate bargain: Each drug manufacturer would agree to pay rebates on all of its drugs paid for under states' Medicaid prescription drug benefits, using a statutory rebate formula designed to lower Medicaid's payments to levels comparable to manufacturers' best terms nationwide. 42 U.S.C. § 1396r-8(a)(1), (c). In return, all of the manufacturer's drugs would be covered under Medicaid, ensuring that Medicaid beneficiaries would have access to the full panoply of prescription drug therapies. *Id.* § 1396r-8(a)(1).[10] In

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[9] *See, e.g., Medicaid Prescription Drug Pricing: Hearing on S. 2605 and S. 3029 before the Senate Subcomm. on Health for Families and the Uninsured of the Comm. on Finance*, 101st Cong. 17, 19, 118, 136-37, 225 (1990) (noting problems with formularies and prior authorization programs).

[10] This tradeoff was spelled out explicitly in the House budget committee report on the bill, which explained:

> The Committee believes that Medicaid, the means-tested entitlement program that purchases basic health care for the poor, should have the benefit of the same discounts on single source drugs that other large public and private purchasers enjoy. The Committee bill would therefore establish a rebate mechanism in order to give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser. Because the Committee is concerned that Medicaid beneficiaries have access to the same range

addition, states would be prohibited from maintaining formularies (lists of drugs for which reimbursement was readily available) that excluded the drugs of participating manufacturers. *Id.* § 1396a(a)(54) (1990).[11]

When Congress in OBRA 90 thus eliminated states' authority to cut costs by restricting beneficiaries' drug coverage, it did permit them to continue to use "prior authorization." See *id.* § 1396r-8(d)(1)(A). At the time, about 25 states used prior authorization, covering an "extremely small number" of drugs for medical-related reasons. See *Medicaid Prescription Drug Pricing: Hearing on S. 2605 and S. 3029 before the Subcomm. on Health for Families and the Uninsured of the Senate Comm. on Finance*, 101st Cong. 225 (1990) (Special Committee on Aging staff materials) ("In general, prior approval programs are used by many states—for a very small percentage of Medicaid-covered prescription drugs—to assure that the prescriptions dispensed are medically necessary."). Congress understood that prior authorization would continue to be used to "safeguard against unnecessary utilization" and to "assure that [Medicaid] payments are consistent with efficiency, economy, and quality of care." H.R. Rep. No. 101-881, at 98, *reprinted in* 1990 U.S.C.C.A.N. at 2110; see also 42 U.S.C. § 1396a(a)(30)(A). Importantly, prior authorization was *not* to be used to undermine Congress's desire to ensure that Medicaid beneficiaries have access to the full range of prescription drugs:

> of drugs that the private patients of their physicians enjoy, the Committee bill would require States that elect to offer prescription drugs to cover all of the products of any manufacturer that agrees to provide price rebates.

H.R. Rep. No. 101-881, at 96-97, *reprinted in* 1990 U.S.C.C.A.N. at 2108-09.

[11] Congress in 1993 restored states' ability to use formularies, but only under tightly controlled conditions. *See* 42 U.S.C. §1396r-8(d)(4).

> However, the Committee does not intend that States establish or implement prior authorization controls that have the effect of preventing competent physicians from prescribing in accordance with their medical judgment. This would defeat the intent of the Committee bill in prohibiting States from excluding coverage of prescription drugs of manufacturers with agreements—i.e. assuring access by Medical [sic] beneficiaries to prescription drugs where medically necessary.

H.R. Rep. No. 101-881, at 98, *reprinted in* 1990 U.S.C.C.A.N. at 2110.

Thus, Congress in OBRA 90 struck a careful balance, trading expanded Medicaid prescription drug coverage for patients (by requiring states to cover all drugs of participating manufacturers, and reining in state cost-cutting restrictions like formularies) for Medicaid rebate payments from manufacturers. See *id.*; *Medicare and Medicaid Budget Reconciliation: Hearings before the Subcomm. on Health and the Env't of the House Comm. on Energy and Commerce,* 103d Cong. 453 (1993) (Rep. Waxman, describing genesis of Medicaid drug rebate program's "government-industry compact").

Here, Maine has unilaterally altered that balance. Demands for Maine Rx rebates are triggered by a manufacturer's very participation in the Medicaid program. 22 Me. Rev. Stat. Ann. § 2681(3) (Pet. App. 87). Previously, a manufacturer entered into a national Medicaid rebate agreement in order to ensure that its drugs would be included in the Medicaid program. Under Maine Rx, that calculus changes: if the manufacturer chooses to participate in the national Medicaid drug program, it must pay rebates for drugs prescribed to Medicaid beneficiaries *and* rebates for drugs prescribed to Maine residents who are not Medicaid beneficiaries. Conversely, a manufacturer cannot avoid the reach of the Maine Rx program unless it pulls out of the national Medicaid program altogether. This diversion of the Medicaid program

to serve non-Medicaid purposes strikes a new balance—one that Congress neither contemplated nor authorized. The national Medicaid program faces significant risks if states can unilaterally alter Congress's terms of participation.[12]

3. Maine Rx's Use Of Medicaid Prior Authorization Serves No Medicaid Purpose.

As the Solicitor General has observed, because prior authorization imposes a burden on Congress's intended beneficiaries, its use can be justified only if it furthers at least *some* Medicaid purpose. U.S. Br. at 13. Maine has disputed that premise, suggesting that because 42 U.S.C. § 1396r-8(d)(1)(A) provides that "[a] State may subject to prior authorization any covered outpatient drug," there is no limit of any kind to the uses to which prior authorization may be put. This is an obvious distortion of Congress's purpose for "prior authorization."

To be sure, the Medicaid statute does not expressly bar states from co-opting Medicaid prior authorization authority for non-Medicaid purposes. But the lack of an express prohibition on using Medicaid powers for non-Medicaid purposes is no license to do so. Congress may have stated that a state can impose prior authorization on covered drugs. See *id.* § 1396r-8(d)(1)(A). But Congress did not say that states can do so for "any reason." The limits on the states' authority are inherent in the structure, object and purpose of the statute.

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[12] 42 U.S.C. § 1396a(a)(30)(A) expresses an analogous concern, when it directs that states must ensure that payments to Medicaid providers "are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population." This provision recognizes that providers' financial incentives (like those of drug manufacturers) must be taken into account in order to assure adequate medical care for Medicaid beneficiaries.

As the district court recognized, the logical reach of a contrary rule—that Medicaid prior authorization can be put to *any* purpose—is untenable: "If Maine can use its authority over Medicaid authorization to leverage [rebates for Maine Rx], then it can just as easily put the rebates into a state program for highway and bridge construction or school funding" (Pet. App. 68). Congress cannot be deemed to have allowed the tools it provided for the operation of the Medicaid program and for the benefit of Medicaid recipients to be used for any other purpose that a state may imagine.

Although Maine cannot plausibly claim that Maine Rx prior authorization is in Medicaid patients' "best interests," Maine has adopted a post-hoc litigating position that Maine Rx may indirectly serve a Medicaid purpose, by perhaps reducing impoverishment of some non-Medicaid Maine residents, thereby potentially keeping them off Medicaid rolls. The court of appeals embraced this rationale, but it fails on two counts.

First, the Medicaid statute itself offers a mechanism for addressing Maine's newfound concerns about persons near to the Medicaid eligibility threshold: the state may seek HHS permission for a Medicaid "demonstration project" to aid those individuals, assuming it can establish to HHS's satisfaction, *inter alia*, that doing so promotes Medicaid objectives. 42 U.S.C. § 1315(a). The Maine Rx program, which is open to all Maine residents rich or poor, is not, and could not pass muster as, a demonstration project. And nowhere in the Maine Rx statute's statement of objectives is there any mention of concern for the fiscal integrity of the Medicaid program, much less any concern for the best interests of Medicaid beneficiaries. 22 Me. Rev. Stat. Ann. § 2681(1) (Pet. App. 86).

Second, if Maine's asserted Medicaid purpose were sufficient, the same reasoning would permit Maine to compel drug manufacturers to subsidize food stamps, public housing, job training programs, and any number of other public

projects that would boost Maine residents' income and thereby potentially keep them off Medicaid. Congress did not intend to invite such broad misuse of the Medicaid program.

At the end of the day, the Solicitor General is correct in observing that "no Medicaid purpose appears to be served" by the Maine Rx program. U.S. Br. at 13. Without a Medicaid purpose, the Maine Rx use of prior authorization is necessarily inconsistent both with the "best interests" of Medicaid patients, 42 U.S.C. § 1396a(a)(19), and the Medicaid program. Maine Rx prior authorization is preempted, for the program cannot possibly be in the "best" interests of Medicaid patients if it serves *no* Medicaid purpose.

II. MAINE'S REBATE REQUIREMENT VIOLATES THE COMMERCE CLAUSE.

Maine had any number of constitutionally legitimate tools at its disposal for reducing drug costs to its citizens. It might have subsidized its citizens' drug purchases out of general revenues. It might have offered them state income tax credits for amounts spent on prescription drugs. And it might even have raised funds for the Maine Rx program by imposing a sales or excise tax directly on all retail pharmacy sales taking place in Maine.

But Maine did none of these things, choosing instead to take all the benefits of Maine Rx for its own citizens while imposing all the costs of its subsidy program on manufacturers residing and transacting virtually entirely out-of-state. This choice violates the Commerce Clause in either or both of two respects.

First, the Commerce Clause, by conferring power to regulate interstate commerce upon Congress, implicitly precludes any state from regulating transactions that take place outside its own borders. In particular, one of the negative implications of the Commerce Clause is that a state "has no power to project its legislation into [another state] by

regulating the price to be paid in that state for [goods] acquired there." *Baldwin* v. *G.A.F. Seelig, Inc.*, 294 U.S. 511, 521 (1935). The Maine Rx program runs afoul of this well-settled extraterritoriality principle by regulating wholesale sales by manufacturers that take place wholly outside of Maine, and by using out-of-state prices as a benchmark for setting in-state rebates.

Second, even if Maine Rx were somehow viewed as regulating activity within Maine's borders, rather than wholesale transactions outside of them, it nonetheless violates the Commerce Clause because it seeks to impose virtually all of the costs of the program on manufacturers located outside Maine while directing all benefit from the program to its own citizens. This Court has struck down similar state attempts to evade the basic antidiscrimination principle of the Commerce Clause by linking an apparently nondiscriminatory levy to a local subsidy. As recently as in *West Lynn Creamery, Inc.* v. *Healy*, 512 U.S. 186, 188 (1994), for example, this Court invalidated as impermissibly discriminatory a Massachusetts milk assessment scheme that charged a premium on all sales of milk to Massachusetts retailers, but rebated all proceeds from this assessment through a special fund to Massachusetts dairy farmers.

A. The Maine Rx Rebate Requirement Constitutes Impermissible Extraterritorial Regulation.

Among the clearest implications of the Commerce Clause is that no state may regulate commerce in another state. In particular, as this Court has confirmed repeatedly, a state may not dictate the terms on which buyers and sellers do business outside the state. See, *e.g.*, *Brown-Forman Distillers Corp.* v. *New York State Liquor Auth.*, 476 U.S. 573, 583-84 (1986); *Healy* v. *Beer Inst., Inc.*, 491 U.S. 324, 338 (1989). Three factors help identify a state statute with an unconstitutional extraterritorial reach or effect that will render it virtually *per se* invalid: (i) whether the regulation is applied to commerce "'wholly outside of the State's borders,'" (ii) whether "the

practical effect" of the regulation is to control such commerce, and (iii) what effect the regulation has on other states' regulations, as well as what effect would result "if not one, but many or every, State adopted similar legislation." *Healy*, 491 U.S. at 336.

Thus, the Commerce Clause prohibits *de facto* extraterritorial state regulation even if the regulation is nominally predicated upon conduct that occurs within the state. That is exactly the case here, where Maine purports to be regulating in-state retail sales of prescription drugs, but in reality is regulating entities far removed (both geographically and commercially) from those pharmacy counter transactions. The critical inquiry—which Maine Rx fails—is whether "the practical effect of the regulation is to control conduct beyond the boundaries of the State." *Id.* Whether the Maine Rx program is characterized as regulating the terms of out-of-state transactions, or as impermissibly tying in-state to out-of-state prices, its practical effect is clearly extraterritorial in violation of the Commerce Clause.

1. Maine Rx Rebates Regulate Wholly Out-Of-State Transactions.

The fundamental holding of *Baldwin*, *Brown-Forman*, and *Healy* is that states may not reach outside their borders to regulate the terms of transactions in other states. Here, Maine mandates payments from manufacturers whose only transactions leading to the pharmacy counter are with wholesalers. To the extent that those sales occur outside Maine—and virtually all manufacturers' sales do—Maine cannot mandate the Maine Rx payments consistent with the Commerce Clause. The only link to the state is that the goods flow through a stream of interstate commerce that the manufacturers do not control and ultimately come to rest on a pharmacy counter in Maine.

States may not regulate the price or terms on which goods are sold outside the state simply because the goods are later

re-sold within the state. Rather, courts have limited the reach of a state's powers to transactions that actually take place within the state. See *Baldwin*, 294 U.S. at 528; *Dean Foods Co.* v. *Brancel*, 187 F.3d 609, 614-15 (7th Cir. 1999); *Louisiana Dairy Stabilization Bd.* v. *Dairy Fresh Corp*., 631 F.2d 67, 69-70 (5th Cir. Unit A 1980), *aff'd*, 454 U.S. 884 (1981); *Schwegmann Bros. Giant Super Mkts.* v. *Louisiana Milk Comm'n*, 365 F. Supp. 1144, 1156 (M.D. La. 1973), *aff'd*, 416 U.S. 922 (1974) (mem.).

Virtually all manufacturers' sales of prescription drugs occur outside of Maine in transactions with wholesalers and distributors (JA 50-51, 56-57, 76-77, 87-88, 110-11). Typically, both the manufacturers and their customers (independent wholesalers and distributors) are located outside Maine. The drugs are usually delivered at the manufacturers' facilities outside Maine, and title and risk of loss pass outside Maine. The drugs are then shipped by common carrier to warehouses and distribution centers outside Maine. The wholesalers and distributors then sell the drugs to their customers, including pharmacies in Maine. Nevertheless, Maine Rx will exact a payment from a drug's manufacturer every time the drug crosses the pharmacy counter in Maine, even though the out-of-state manufacturer sold that product outside Maine to a wholesaler in another state and had no further role in the transactions that took the drugs to Maine.

The Maine Rx rebate has an effect similar to that of a duty imposed at the state's border: it reduces the effective price received by the manufacturer outside Maine on the units of its drugs that are eventually sold in Maine. That levy necessarily changes the economic terms of the only sales transactions in which manufacturers *are* engaged—namely, sales outside the state—by effectively reducing the revenues the manufacturers receive for their products from their wholesale customers. The manufacturer who is assessed the rebate will receive less net revenue on each wholesale transaction involving drugs that find their way to Maine (a result the manufacturer does

not control and cannot predict). As the district court recognized, "whatever price the manufacturer originally received for that out-of-state transaction is automatically reduced when the drug comes to Maine" (Pet. App. 66).

The First Circuit erroneously treated the Maine Rx rebate requirement as a regulation of the retail pharmacy sale of drugs, which does occur in Maine (Pet. App. 24). Maine has similarly suggested that Maine Rx rebates regulate the in-state retail sales, and have merely "incidental" effects on out-of-state manufacturers and their out-of-state wholesale transactions. Opp. Cert. at 20-21. Such a reading flies in the face of the statute. Other aspects of the Act, such as the provisions governing the prices to be charged by pharmacies to Maine Rx participants, 22 Me. Rev. Stat. Ann. § 2681(5) (Pet. App. 88-89), undoubtedly do regulate the pharmacy sales in Maine. But the exaction of "rebates" from manufacturers has no effect on, and is not directed to any party to, those in-state retail sales. The ultimate retail sales of the manufacturers' products merely generate the data that the state uses to calculate the dollar amount demanded directly, not "incidentally," from the manufacturers. When that demand is directed to out-of-state manufacturers based on their out-of-state sales, it violates the territorial limits of Maine's legislative authority under the Commerce Clause. The "practical effect" of the Act is to regulate the manufacturer's commerce occurring "wholly outside of the state's borders." *Healy*, 491 U.S. at 336.

If Maine's position were to prevail, then the state could well send a bill to any manufacturer of any product located anywhere in the country any time that manufacturer's product is sold—not by the manufacturer, but by others—in Maine. If the Maine legislature decides that the price of heating oil is too high, it might demand "rebates" from refineries in Texas whose output is sold to distributors who ship it to Maine. If the state chooses to promote computer literacy, it might demand "rebates" from California semiconductor

manufacturers whose chips end up in computers sold in Maine. Such schemes would obviously transgress the boundaries established by the Commerce Clause.

These boundaries are further illustrated by analogy to this Court's cases reading the Commerce Clause to limit the territorial reach of a state's taxation power. Because Maine Rx compels a payment to the state in connection with each sale of prescription drugs in Maine pharmacies to a Maine Rx cardholder, it resembles a sales tax. Were the Maine Rx rebate requirement to be assessed by the standards of this Court's interstate sales tax cases, however, it could not stand. See, *e.g.*, *Quill Corp.* v. *North Dakota ex rel Heitkamp,* 504 U.S. 298, 311, 315 (1992) (vendor whose only connection with customers in the taxing state is by mail or common carrier lacks substantial nexus required by Commerce Clause to impose sales tax liability) (citing *National Bellas Hess, Inc.* v. *Department of Revenue*, 386 U.S. 753 (1967) (overruled in part on other grounds)); *McLeod* v. *J.E. Dilworth Co.*, 322 U.S. 327, 330 (1944) (rejecting Arkansas efforts to impose sales tax liability on out-of-state vendor whose products were delivered into the state via common carrier); cf. *American Oil Co.* v. *P.G. Neill*, 380 U.S. 451, 457 (1965) (noting that the Court has "[m]ore than once … struck down taxes directly imposed on or resulting from out-of-state sales which were held to be insufficiently related to activities within the taxing state, despite the fact that the vendor knew that the goods were destined for use in that State").

The basic framework of *Complete Auto Transit, Inc.* v. *Brady*, 430 U.S. 274 (1977), and its companion cases establishes that Maine may not tax out-of-state transactions unrelated to the state, nor impose sales tax liability on an out-of-state manufacturer merely because its products are sold in Maine by an unrelated third party. Under *Complete Auto*, only taxes that "[1] [are] applied to an activity with a substantial nexus with the taxing State, [2] [are] fairly apportioned, [3] do[] not discriminate against interstate

commerce, and [4] [are] fairly related to the services provided by the State" will survive Commerce Clause scrutiny. *Id.* at 279.

At a minimum, the Maine Rx program would fail the first of the *Complete Auto* elements. The Maine Rx rebate "taxes" drug manufacturers when third parties sell the manufacturers' products in Maine. While Maine clearly has the authority to tax in-state retail pharmaceutical sales, and may tax either the individual purchasers or the Maine-based pharmacies that sell drugs manufactured by PhRMA's members, it may not require out-of-state manufacturers who are strangers to the in-state retail transactions to bear the costs of this activity. Thus, if Maine purports to tax the only "activity with a substantial nexus to the taxing state" (*i.e.*, the retail sales), it may not impose this liability on out-of-state entities that are not involved in or responsible for that in-state activity.

Alternatively, if Maine purports to be taxing the "activity" of manufacturers—namely, wholesale sales—the Maine Rx rebate requirement even more obviously fails *Complete Auto*'s nexus requirement. Maine may not require out-of-state manufacturers to pay sales taxes on out-of-state wholesale transactions that have no relationship to the state of Maine. As noted *supra* at 29, virtually all of PhRMA members' product sales occur outside of Maine, in arms-length transactions with wholesalers and distributors, in which title and the risk of loss pass outside of the state. The activity in which the manufacturers are engaged thus has no nexus, much less a substantial one, to Maine.

2. Maine Rx Rebates Are Impermissibly Tied To Out-Of-State Prices.

The Maine Rx rebates separately violate the Commerce Clause because they impermissibly use out-of-state prices as a benchmark. The Act specifies that the "rebate required from … manufacturer[s]" is to equal or exceed the rebates required around the country under Medicaid and other federal

programs. 22 Me. Rev. Stat. Ann. § 2681(3), (4) (Pet. App. 87-88). Thus, the rebates that manufacturers must pay to Maine are tied to the rebates that manufacturers pay and prices they charge around the country.

This use of an out-of-state price benchmark for Maine's in-state mandatory rebate offends the principle set forth in *Brown-Forman* and *Healy*. In *Brown-Forman*, the Court struck down a New York law preventing distillers from varying their prices in a given month, and requiring an affirmation that the price in a each month was the lowest price at which the distiller would sell anywhere else in the United States. 476 U.S. at 575-76, 583-84. In *Healy*, the offending Connecticut law required beer distributors to certify that their in-state prices did not exceed prices charged in neighboring states. 491 U.S. at 328-29. In both cases, the law nominally regulated in-state activity, but had the effect of regulating prices outside the state.

The key offensive element of the price affirmation statutes in *Brown-Forman* and *Healy* was their effect on consumers and the competitive market in other states. The sellers in New York and Connecticut were prevented from setting prices in other states based solely on the competitive conditions prevailing there. If they lowered their prices in other states, they would have to change their New York and Connecticut prices as well; the in-state affirmation statutes altered their out-of-state pricing calculations.

As the Court explained in *Brown-Forman*, such state statutes, like the one here, are a form of protectionism toward in-state consumers: New York and Connecticut were advantaging their own consumers by depriving purchasers in other states of the benefits of local marketplace conditions. "While a State may seek lower prices for its consumers, it may not insist that producers or consumers in other States surrender whatever competitive advantages they may possess." 476 U.S. at 580; see also *Healy*, 491 U.S. at 339 (holding the Commerce Clause violated as the statute

"requires out-of-state shippers to forgo the implementation of competitive-pricing schemes in out-of-state markets because those pricing decisions are imported by statute into the Connecticut market regardless of local competitive conditions"). The Court thus condemned the price-tying on a *per se* basis—*i.e.*, as a direct regulation of out-of-state commerce—because it interfered with market-based competition in the out-of-state markets. See *Brown-Forman*, 476 U.S. at 580; *Healy*, 491 U.S. at 332.

Maine Rx's price tying operates in a similar way. By linking Maine Rx rebate levels to the federal Medicaid rebate level and to the lowest prices charged to the federal government, 22 Me. Rev. Stat. Ann. § 2681(3), (4) (Pet. App. 87-88), Maine is intruding into drug manufacturers' pricing decisions elsewhere in the nation. These two federal benchmarks give rise to the same kind of market pricing dynamics and extraterritorial effects that the Court condemned in *Healy* and *Brown-Forman*. The effect of the federal price benchmark, *id.* § 2681(4)(C) (Pet. App. 88), is straightforward: A manufacturer cannot charge a lower price to the federal government based *solely* on market conditions, because it also has to take into account the fact that the lower federal price will directly trigger a larger Maine Rx rebate.

The effect of the Medicaid benchmark, *id.* § 2681(4)(B) (Pet. App. 88), is the same, although slightly more complex in its operation: The Medicaid rebate amount for each brand-name drug is a function of the manufacturer's pricing decisions around the country. The statute bases the rebate on a manufacturer's national average price and the manufacturer's "best price" to a customer anywhere in the country. 42 U.S.C. § 1396r-8(c)(1). A drug manufacturer cannot lower prices charged to customers in California or Texas without taking into account the impact of those changes on the rebate it will owe to Maine. Previously, a new, lower "best price" would change only the rebates owed in the Medicaid program, a federal program in which the interests of

the residents of all states are represented. Now, however, Maine has unilaterally "project[ed] its legislation into [other states]," *Baldwin*, 294 U.S. at 521, because price changes in other states will change the rebates owed in Maine Rx as well.

Both Maine Rx benchmarks mean that a drug manufacturer can no longer set its out-of-state prices based solely on the out-of-state market conditions. Instead, when setting prices in out-of-state transactions, the drug manufacturer now must also factor the Maine rebate ramifications into its federal and nationwide pricing calculations. Even if that new factor may be a small one when it is only prescriptions for the 1.3 million residents of Maine at stake, there is no *de minimis* safe harbor for extraterritorial regulation under the Commerce Clause. Maine is no more entitled to regulate outside its borders than is California or Florida. Furthermore, if Maine's scheme is upheld, other states will surely follow Maine's lead and link in-state rebate demands to the federal Medicaid rebate level, drastically exacerbating the interference with "competitive pricing … based on prevailing market conditions," *Healy*, 491 U.S. at 338.

In sum, this Court's *Brown-Forman* and *Healy* precedents require the invalidation of the Maine Rx rebate program on the ground that it impermissibly fetters out-of-state price terms, interfering with interstate commerce.

B. The Maine Rx Rebate Requirement Impermissibly Discriminates Against Interstate Commerce In Order To Subsidize In-State Consumers.

Even if Maine Rx rebates were held not to operate extraterritorially, the Maine Rx program nonetheless violates the Commerce Clause because it externalizes the costs and internalizes the benefits of the program in a manner that, taken as a whole, is impermissibly discriminatory.

It is well-settled under the Commerce Clause that a state may not selectively exempt local economic actors from

generally applicable burdens. See, *e.g.*, *Bacchus Imps. Ltd.* v. *Dias*, 468 U.S. 263, 265 (1984) (invalidating exemption from Hawaii liquor tax for beverages produced only locally); *New Energy Co.* v. *Limbach*, 486 U.S. 269, 279-80 (1988) (invalidating a fuel tax credit solely for ethanol produced in-state). Furthermore, the Court explained in *West Lynn*, 512 U.S. at 188, that a state may not evade this antidiscrimination principle by using a two-step process of imposing a general burden, but using its proceeds to furnish a subsidy solely to in-state economic interests.

West Lynn invalidated a Massachusetts milk pricing order that levied an assessment on all retail sales of milk in Massachusetts (most of which was produced out of state), placed the proceeds in a segregated fund, and distributed that fund in turn to Massachusetts dairy farmers. The Court held this linked charge-and-subsidy scheme to be impermissibly discriminatory, even if a nondiscriminatory charge and a cash subsidy independently would each have been constitutional. The Court explained:

> Even granting respondent's assertion that both components of the pricing order would be constitutional standing alone, the pricing order nevertheless must fall. A pure subsidy funded out of general revenue ordinarily imposes no burden on interstate commerce, but merely assists local business. The pricing order in this case, however, is funded principally from taxes on the sale of milk produced in other States. By so funding the subsidy, respondent not only assists local farmers, but burdens interstate commerce.

Id. at 199 (footnotes omitted).

This case is analogous to *West Lynn* and should reach the same result under the Commerce Clause. Here, as in *West Lynn*, the state has imposed a requirement for payments whose incidence falls overwhelmingly on out-of-state manufacturers. Here, as in *West Lynn*, the state segregates all

the proceeds of that assessment in a separate "dedicated" fund apart from its general treasury. See *id.* at 210-12 (Scalia, J., concurring in judgment) (emphasizing this distinction). And here, as in *West Lynn*, the state remits rebates from that fund solely to in-state economic interests—here, to in-state retail pharmacists and to in-state consumers. Thus, here, as in *West Lynn*, the state's decision to force out-of-state interests to bear the cost of a subsidy created for the state's own citizens should be invalidated.

Moreover, Maine Rx implicates the concerns stated long ago by Chief Justice Stone, who wrote that "the court has often recognized that to the extent … the burden of state regulation falls on interests outside the state, it is unlikely to be alleviated by the operation of those political restraints normally exerted when interests within the state are affected." *Southern Pac. Co.* v. *Arizona ex rel. Sullivan*, 325 U.S. 761, 767 n.2 (1945). There is even less reason here than in *West Lynn* to expect in-state political processes to safeguard the interests of interstate commerce. As the Court noted there:

> when a nondiscriminatory tax is coupled with a subsidy to one of the groups hurt by the tax, a State's political processes can no longer be relied upon to prevent legislative abuse, because one of the in-state interests which would otherwise lobby against the tax has been mollified by the subsidy.

West Lynn, 512 U.S. at 200. In the Massachusetts case, "dairy farmers, milk dealers, and consumers" should all have lobbied against the milk premium, "[b]ut because the tax was coupled with a subsidy, one of the most powerful of these groups, Massachusetts dairy farmers, instead of exerting their influence against the tax, were in fact its primary supporters." *Id.* at 200-01. Here, no local forces exist to protect the interests of out-of-state manufacturers or out-of-state consumers in the political process: Maine consumers obviously benefit directly from the subsidy, while Maine retail pharmacists, who might otherwise be concerned about

facing higher prices, are "mollified" by the state's transfer to them of Maine Rx rebates and a $3 "professional fee" for each prescription.

To be sure, *West Lynn* differs from this case in one respect: there, Massachusetts sought to enable high-cost local milk producers to compete with lower-cost milk producers located outside the state, which the Court analogized to imposition of a tariff on out-of-state milk. See *id.* at 194-95. Here, there are no Maine pharmaceutical manufacturers to be similarly protected. But that feature was neither necessary nor dispositive in *West Lynn*. To the contrary, *West Lynn* expressly rejected Massachusetts' argument that its scheme was not discriminatory because the milk dealers who paid the tax did not compete with the dairy farmers who reaped the subsidy. The Court reasoned that what matters is the burden that discrimination places "on any part of the stream of commerce—from wholesaler to retailer to consumer[.] [A] burden placed at any point will result in a disadvantage to the out-of-state producer." *Id.* at 202.

In sum, the Maine Rx rebate scheme represents a new variation on state efforts to externalize the costs of local subsidies upon out-of-state economic interests. Accordingly, it is barred by the Commerce Clause.

CONCLUSION

For the foregoing reasons, the decision of the court of appeals should be reversed.

Respectfully submitted,

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